Terrestrial Animal Health Standards Commission Report February 2015

NOTE:
The Code Commission encourages Member Countries to review all relevant reports when reviewing this document including the following:

- September 2014 report of the Scientific Commission for the rationale on the proposed amendments (http://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/SCAD/A_SCAD_Sept2014.pdf)
- August 2013 report of the *ad hoc* Group on Harmonization of Vector-Borne Diseases attached to the Scientific Commission report (http://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/SCAD/A_SCAD_Sept2013.pdf)

CHAPTER 8.3.

INFECTION WITH BLUETONGUE VIRUS~~ES~~

Article 8.3.1.

General provisions

For the purposes of the *Terrestrial Code*, bluetongue is defined as an *infection* of ~~A *case* refers to an~~ ruminants and camelids ~~*animal* infected~~ with ~~BT~~ bluetongue virus (BTV), that is transmitted by *Culicoides vectors*.

The following defines an *infection* with ~~the occurrence of~~ BTV ~~*infection*~~:

1) BTV, including naturally transmitted vaccine strains, has been isolated ~~and identified as such~~ from ~~an *animal*~~ ruminant or camelid or a product derived from that ~~*animal*~~ ruminant or camelid, or

2) viral antigen or viral ribonucleic acid ~~(RNA)~~ specific to ~~one or more of the serotypes of~~ BTV has been identified in samples from ~~one or more *animals*~~ a ruminant or camelid showing clinical signs consistent with bluetongue ~~BT~~, or epidemiologically linked to a ~~confirmed~~suspected or ~~suspected~~ confirmed *case*~~, or giving cause for suspicion of previous association or contact with BTV~~, or

3) antibodies to structural or nonstructural proteins of BTV that are not a consequence of *vaccination* have been identified in ~~one or more *animals*~~ a ruminant or camelid that either shows clinical signs consistent with ~~BT~~ bluetongue, or is epidemiologically linked to a suspected ~~confirmed~~ or ~~suspected~~ confirmed *case*, ~~or give cause for suspicion of previous association or contact with BTV~~.

~~For the purposes of *international trade*, a distinction should be made between a *case* as defined above and an *animal* that is potentially infectious to *vectors*.~~

For the purposes of the *Terrestrial Code*, the *infective period* for ~~bluetongue viruses (~~BTV~~)~~ shall be 60 days.

~~Historically, the global BTV distribution has been confined between the latitudes of approximately 53°N and north of 34°S with a recent extension in Northern Europe.~~

~~In the absence of clinical *disease* in a country or *zone*, its BTV status should be determined by an ongoing *surveillance* programme (in accordance with Articles 8.3.16. to 8.3.21.). The programme may need to be adapted to target parts of the country or *zone* at a higher risk due to historical, geographical and climatic factors, ruminant population data and *Culicoides* ecology, or proximity to enzootic or incursional zones as described in Articles 8.3.16. to 8.3.21.~~

~~All countries or *zones* adjacent to a country or *zone* not having free status should be subjected to similar *surveillance*. The *surveillance* should be carried out over a distance of at least 100 kilometres from the border with that country or *zone*, but a lesser distance could be acceptable if there are relevant ecological or geographical features likely to interrupt the transmission of BTV or a bluetongue *surveillance* programme (in accordance with Articles 8.3.16. to 8.3.21.) in the country or *zone* not having free status supports a lesser distance.~~

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

When authorising import or transit of the *commodities* covered in the chapter, with the exception of those listed in Article 8.3.2., *Veterinary Authorities* should require the conditions prescribed in this chapter relevant to the BTV status of the ruminant and camelid populations of the *exporting country* or *zone*.

Article 8.3.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any BTV related conditions regardless of the BTV status ~~of the ruminant population~~ of the *exporting country* ~~or *zone*~~:

1) *milk* and *milk products*;

2) *meat* and *meat products*;

3) hides and skins;

4) wool and fibre;

5) *in vivo* derived bovine embryos ~~and oocytes~~ collected, processed and stored in ~~conformity~~ accordance with ~~the provisions of~~ Chapter 4.7. ~~except for BTV8 (under study)~~.

Article 8.3.3.

BTV free c

ountry or zone

1) Historical freedom as described in Chapter 1.4. does not apply to *infection* with BTV.

2~~1~~) A country or a *zone* may be considered free ~~from BTV~~ when ~~bluetongue~~ *infection* with BTV is notifiable in the whole country and either:

a) a *surveillance* programme in accordance with Articles 8.3.~~16~~14. to 8.3.~~21~~17. has demonstrated no evidence of BTV *infection* in the country or *zone* during the past two years; or

b) an ongoing *surveillance* programme has ~~demonstrated~~ found no ~~evidence of~~ *Culicoides* for at least two years in the country or *zone*.

3~~2~~) A BTV free country or *zone* in which ongoing *vector surveillance*, performed according to point 5 of Article 8.3.~~19~~16., has found no ~~evidence of~~ *Culicoides* will not lose its free status through the ~~importation~~ introduction of vaccinated, seropositive or infective ~~*animals*~~ ruminants or camelids, or their semen~~, or~~ embryos~~/~~or ~~ova~~oocytes from infected countries or infected *zones*.

4~~3~~) A BTV free country or *zone* in which *surveillance* has found evidence that *Culicoides* are present will not lose its free status through the ~~importation~~ introduction of ~~vaccinated or~~ seropositive or vaccinated ~~*animals*~~ ruminants or camelids, or semen, embryos, or oocytes from infected countries or infected *zones*, provided:

a) an ongoing *surveillance* programme focused on BTV transmission and a consideration of the epidemiology of BTV *infection*, in accordance with Articles 8.3.14. to 8.3.17. and Chapter 4.3., has demonstrated no evidence of BTV transmission in the country or *zone*; or

b) the ruminants or camelids, their semen, embryos and oocytes were introduced in accordance with this chapter.

~~a) the *animals* have been vaccinated, at least 60 days prior to dispatch, in accordance with the *Terrestrial Manual* with a vaccine which covers all serotypes whose presence in the source population has been demonstrated through a *surveillance* programme in accordance with Articles 8.3.16. to 8.3.21., and the *animals* are identified in the accompanying certification as having been vaccinated; or~~

~~b) the *animals* are not vaccinated and, at least 60 days prior to dispatch, are demonstrated to have specific antibodies against the bluetongue virus serotypes whose presence has been demonstrated in the *exporting country* or *zone*.~~

5~~4~~) A BTV free country or *zone* adjacent to an infected country or infected *zone* should include a *zone* ~~as described in Article 8.3.1.~~ in which *surveillance* is conducted in accordance with Articles 8.3.~~16~~14. to 8.3.~~21~~17. ~~*Animals* within this *zone* should be subjected to continuing *surveillance*. The boundaries of this *zone* should be clearly defined, and should take account of geographical and epidemiological factors that are relevant to BTV transmission.~~

Article 8.3.4.

BTV seasonally free zone

A BTV seasonally free *zone* is a part of an infected country or an infected *zone* for which ~~for part of a year,~~ *surveillance* demonstrates no evidence either of BTV transmission or of adult *Culicoides* for part of a year.

For the application of Articles 8.3.7., 8.3.~~10~~9. and 8.3.~~13~~11., the seasonally free period is taken to commence the day following the last evidence of BTV transmission (as demonstrated by the *surveillance* programme), and of the cessation of activity of adult *Culicoides*.

For the application of Articles 8.3.7., 8.3.~~10~~9. and 8.3.~~13~~11., the seasonally free period is taken to conclude either:

1) at least 28 days before the earliest date that historical data show ~~bluetongue virus~~BTV ~~activity~~ transmission ~~has~~may recommence~~d~~; or

2) immediately if current climatic data or data from a *surveillance* programme indicate an earlier resurgence of activity of adult *Culicoides*.

A BTV seasonally free *zone* in which ongoing *surveillance* has found no evidence that *Culicoides* are present will not lose its free status through the ~~importation~~ introduction of vaccinated, seropositive or infective ~~*animals*~~ ruminants or camelids, or semen~~.~~ ~~or~~ embryos~~/~~ or ~~ova~~oocytes from infected countries or infected *zones*.

Article 8.3.5.

BTV infected country or zone

For the purposes of this chapter, a BTV infected country or infected *zone* is ~~a clearly defined area where evidence of BTV has been reported during the past two years.~~ one that does not fulfil the requirements to qualify as either BTV free country or *zone* or BTV seasonally free *zone*~~. Such a country or *zone* may contain a BTV seasonally free *zone*~~.

Article 8.3.6.

Recommendations for importation from BTV free countries or zones

For ruminants and camelids~~other BTV susceptible herbivores~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the animals showed no clinical sign of BT on the day of shipment;

2~~1~~) the animals were kept in a BTV free country or *zone* since birth or for at least 60 days prior to shipment; or

3~~2~~) the animals were kept in a BTV free country or *zone* for at least 28 days, then were subjected, with negative results, to a serological test to detect antibodies to the BTV group ~~according to the *Terrestrial Manual*~~ and remained in the BTV free country or *zone* until shipment; or

4~~3~~) the animals were kept in a BTV free country or *zone* for at least ~~seven~~14 days, then were subjected, with negative results, to an agent identification test ~~according to the *Terrestrial Manual*~~, and remained in the BTV free country or *zone* until shipment; or

5~~4~~) the animals:

a) were kept in a BTV free country or *zone* for at least seven days;

b) were vaccinated, at least 60 days before the introduction into the free country or *zone*, ~~in accordance with the *Terrestrial Manual*~~ against all serotypes ~~whose~~ ~~presence~~ demonstrated to be present in the source population ~~has been demonstrated~~ through a *surveillance* programme as described in Articles 8.3.~~16~~14. to 8.3.~~21~~17.;

c) were identified as having been vaccinated; ~~and~~

d) remained in the BTV free country or *zone* until shipment;

AND

65) if the animals were exported from a free *zone* within an infected country, either:

a) did not transit through an infected *zone* during transportation to the *place of shipment*; or

b) were protected from attack from *Culicoides* at all times when transiting through an infected *zone*; or

c) had been vaccinated in accordance with point 54 above.

Article 8.3.7.

Recommendations for importation from BTV seasonally free zones

For ruminants and ~~other BTV susceptible herbivores~~camelids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1) showed no clinical sign of BT on the day of shipment;

21) were kept during the seasonally free period in a BTV seasonally free *zone* since birth or for at least 60 days prior to shipment; or

32) were kept during the BTV seasonally free period in a BTV seasonally free *zone* for at least 28 days prior to shipment, and were subjected during the residence period in the *zone* to a serological test to detect antibodies to the BTV group ~~according to the *Terrestrial Manual*~~, with negative results, carried out at least 28 days after the commencement of the residence period; or

43) were kept during the BTV seasonally free period in a BTV seasonally free *zone* for at least 14 days prior to shipment, and were subjected during the residence period in the *zone* to an agent identification test ~~according to the *Terrestrial Manual*~~, with negative results, carried out at least 14 days after the commencement of the residence period; or

54) were kept during the seasonally free period in a BTV seasonally free *zone* and were vaccinated, at least 60 days before the introduction into the free country or *zone*, ~~in accordance with the *Terrestrial Manual*~~ against all serotypes ~~whose presence~~ demonstrated to be present in the source population ~~has been demonstrated~~ through a *surveillance* programme in accordance with Articles 8.3.1~~6~~14. to 8.3.~~21~~17. and were identified as having been vaccinated and remained in the BTV seasonally free country or *zone* until shipment;

AND

65) either:

a) did not transit through an infected *zone* during transportation to the *place of shipment*; or

b) were protected from attack from *Culicoides* at all times when transiting through an infected *zone*; or

c) were vaccinated in accordance with point 54 above.

Article 8.3.8.

Recommendations for importation from BTV infected countries or zones

For ruminants and ~~other BTV-susceptible herbivores~~camelids

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that the animals:

1) showed no clinical sign of BT on the day of shipment;

2~~1~~) were protected from attack from *Culicoides* in a *vector*-protected *establishment* for at least 60 days prior to shipment and during transportation to the *place of shipment*; or

3~~2~~) were protected from attack from *Culicoides* in a *vector*-protected *establishment* for at least 28 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to a serological test ~~according to the *Terrestrial Manual*~~ to detect antibodies to the BTV group, with negative results, carried out at least 28 days after introduction into the *vector*-protected *establishment*; or

4~~3~~) were protected from attack from *Culicoides* in a *vector*-protected *establishment* for at least 14 days prior to shipment and during transportation to the *place of shipment*, and were subjected during that period to an agent identification test ~~according to the *Terrestrial Manual*~~, with negative results, carried out at least 14 days after introduction into the *vector*-protected *establishment*; or

5~~4~~) were vaccinated, at least 60 days before shipment, ~~according to the *Terrestrial Manual*~~ against all serotypes ~~whose presence~~ demonstrated to be present in the source population ~~has been demonstrated~~ through a *surveillance* programme in accordance with Articles 8.3.1~~6~~14. to 8.3.~~21~~17~~.~~, ~~and were identified in the accompanying certification as having been vaccinated or, if demonstrated to have antibodies, have been protected from vectors for at least 60 days prior to shipment~~; or

6~~5~~) were demonstrated to have antibodies for at least 60 days prior to dispatch against all serotypes ~~whose presence has been~~ demonstrated to be present in the source population through a *surveillance* programme in accordance with Articles 8.3.1~~6~~14. to 8.3.~~21~~17.

Article 8.3.9.

Recommendations for importation from BTV free countries or zones or from BTV seasonally free zones

For semen of ruminants and camelids~~other BTV-susceptible herbivores~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor ~~*animals*~~ males:

   a) showed no clinical sign of bluetongue on the day of collection;

   b~~a~~) were kept in a BTV free country or *zone* or during the BTV seasonally free period in a BTV seasonally free *zone* for at least 60 days before commencement of, and during, collection of the semen; or

   c~~b~~) were subjected to a serological test ~~according to the *Terrestrial Manual*~~ to detect antibodies to the BTV group, with negative results, between ~~21~~28 and 60 days after the last collection for this consignment ~~with negative results~~, and, in case of a BTV seasonally free *zone*, at least every 60 days throughout the collection period; or

   d~~c~~) were subjected to an agent identification test ~~according to the *Terrestrial Manual*~~ on blood samples collected at commencement and conclusion of, and at least every ~~7~~ seven days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2) the semen was collected, processed and stored in ~~conformity~~ accordance with ~~the provisions of~~ Chapters 4.5. and 4.6.

~~Article 8.3.10.~~

~~**Recommendations for importation from BTV seasonally free zones**~~

~~For semen of ruminants and other BTV susceptible herbivores~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:~~

~~1) the donor *animals*:~~

~~a) were kept during the BTV seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the semen; or~~

~~b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, with negative results, at least every 60 days throughout the collection period and between 21 and 60 days after the final collection for this consignment; or~~

~~c) were subjected to an agent identification test according to the *Terrestrial Manual* on blood samples collected at commencement and conclusion of, and at least every 7 days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;~~

~~2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.~~

Article 8.3.~~11~~.10.

Recommendations for importation from BTV infected countries or zones

For semen of ruminants and camelids~~other BTV susceptible herbivores~~

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor ~~*animals*~~ males:

a) showed no clinical sign of bluetongue on the day of collection;

b~~a~~) were kept in a *vector*-protected *establishment* for at least 60 days before commencement of, and during, collection of the semen; or

c~~b~~) were subjected to a serological test ~~according to the *Terrestrial Manual*~~ to detect antibodies to the BTV group, with negative results, at least every 60 days throughout the collection period and between ~~21~~28 and 60 days after the final collection for this consignment; or

d~~c~~) were subjected to an agent identification test ~~according to the *Terrestrial Manual*~~ on blood samples collected at commencement and conclusion of, and at least every ~~7~~ seven days (virus isolation test) or at least every 28 days (PCR test) during, semen collection for this consignment, with negative results;

2) the semen was collected, processed and stored in ~~conformity~~ accordance with ~~the provisions of~~ Chapters 4.5. and 4.6.

Article 8.3.~~12~~11.

Recommendations for importation from BTV free countries or zones or from BTV seasonally free zones

For *in vivo* derived embryos of ruminants (other than bovine~~s~~ embryos) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females:

a) showed no clinical sign of bluetongue on the day of collection;

b~~a~~) were kept in a BTV free country or *zone* or during the seasonally free period in a seasonally free *zone* for at least the 60 days prior to, and at the time of, collection of the embryos; or

cb) were subjected to a serological test ~~according to the *Terrestrial Manual*~~ to detect antibodies to the BTV group, between ~~21~~28 and 60 days after collection, with negative results; or

dc) were subjected to an agent identification test ~~according to the *Terrestrial Manual*~~ on a blood sample taken on the day of collection, with negative results;

2) the embryos were collected, processed and stored in ~~conformity~~ accordance with ~~the provisions of~~ Chapters 4.7., 4.8. and 4.9., as relevant.

~~Article 8.3.13.~~

~~**Recommendations for importation from BTV seasonally free zones**~~

~~For *in vivo* derived embryos/ or oocytes of ruminants (other than bovines) and other BTV susceptible herbivores and for *in vitro* produced bovine embryos~~

~~*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:~~

~~1) the donor females:~~

~~a) were kept during the seasonally free period in a seasonally free *zone* for at least 60 days before commencement of, and during, collection of the embryos/ or oocytes; or~~

~~b) were subjected to a serological test according to the *Terrestrial Manual* to detect antibody to the BTV group, between 21 and 60 days after collection, with negative results; or~~

~~c) were subjected to an agent identification test according to the *Terrestrial Manual* on a blood sample taken on the day of collection, with negative results;~~

~~2) the embryos/ or oocytes were collected, processed and stored in conformity with the provisions of Chapters 4.7., 4.8. and 4.9., as relevant.~~

Article 8.3.~~14~~12.

Recommendations for importation from BTV infected countries or zones

For *in vivo* derived embryos~~/~~ or oocytes of ruminants (other than bovine~~s~~ embryos) and other BTV susceptible animals and for *in vitro* produced bovine embryos

Veterinary Authorities should require the presentation of an *international veterinary certificate* attesting that:

1) the donor females:

a) showed no clinical sign of bluetongue on the day of collection;

ba) were kept in a *vector*-protected *establishment* for at least 60 days before commencement of, and during, collection of the embryos~~/~~ or oocytes; or

cb) were subjected to a serological test ~~according to the *Terrestrial Manual*~~ to detect antibodies to the BTV group, between ~~21~~28 and 60 days after collection, with negative results; or

dc) were subjected to an agent identification test ~~according to the *Terrestrial Manual*~~ on a blood sample taken on the day of collection, with negative results;

2) the embryos~~/~~ or oocytes were collected, processed and stored in ~~conformity~~ accordance with ~~the provisions of~~ Chapters 4.7., 4.8. and 4.9., as relevant~~.~~;

3) semen used to fertilise the oocytes complied with Article 8.3.9.

Article 8.3.~~15~~13.

Protecting animals from Culicoides attack

1. Vector-protected establishment or facility

The *establishment* or facility should be approved by the *Veterinary Authority* and the means of protection ~~of the *establishment* or facility~~ should at least comprise the following:

a) appropriate physical barriers at entry and exit points, e.g. double-door entry-exit system;

b) openings of the building are *vector* screened with mesh of appropriate gauge impregnated regularly with an approved insecticide according to ~~the~~ manufacturers' instructions;

c) *vector surveillance* and control within and around the building;

d) measures to limit or eliminate breeding sites for *vectors* in the vicinity of the *establishment* or facility;

e) standard operating procedures, including description of back-up and alarm systems, for operation of the *establishment* or facility and transport of animals to the place of *loading*.

2. During transportation

When transporting animals through BTV infected countries or infected *zones*, *Veterinary Authorities* should require strategies to protect animals from attack from *Culicoides* during transport, taking into account the local ecology of the *vector*.

a) Transport by road

~~Potential~~ R~~r~~*isk management* strategies may include:

i~~a~~) treating animals with insect repellents prior to and during transportation;

ii~~b~~) *loading*, transporting and *unloading* animals at times of low *vector* activity (i.e. bright sunshine, low temperature);

iii~~c~~) ensuring *vehicles* do not stop en route during dawn or dusk, or overnight, unless the animals are held behind insect proof netting;

iv~~d~~) darkening the interior of the *vehicle*, for example by covering the roof ~~and/~~or sides of *vehicles* with shade cloth;

v~~e~~) *surveillance* for *vectors* at common stopping and ~~offloading~~ *unloading* points to gain information on seasonal variations;

vi~~f~~) using historical information ~~and/~~or information from appropriately verified and validated ~~BTV~~ bluetongue epidemiological models to identify low risk ports and transport routes.

b) Transport by air

Prior to *loading* the animals, the crates, containers or jet stalls should be sprayed with an insecticide approved in the country of dispatch.

Crates, containers or jet stalls in which animals are being transported and the cargo hold of the aircraft should be sprayed with an approved insecticide when the doors have been closed and prior to take-off. All possible insect harbourage should be treated. The spray containers should be retained for inspection on arrival.

In addition, during any stopover in countries or *zones* not free from bluetongue prior to the opening of any aircraft door and until all doors are closed, netting of appropriate gauge impregnated with an approved insecticide should be placed over crates, containers or jet stalls.

Article 8.3.~~16~~14.

Introduction to s~~S~~urveillance~~: introduction~~

~~The purpose of *surveillance* is the detection of virus circulation in a country or *zone* and not determination of the status of an individual *animal* or *herds*. *Surveillance* deals not only with the occurrence of clinical signs caused by BTV, but also with the evidence of *infection* with BTV in the absence of clinical signs.~~

Articles 8.3.~~16~~14. to 8.3.~~21~~17. define the principles and provide ~~a guide~~ guidance on ~~the~~ *surveillance* for *infection* with BTV, complementary to Chapter 1.4. and for *vectors* complementary to Chapter 1.5.~~, applicable to Members seeking to determine their BT status. This may be for the entire country or *zone*. Guidance for Members seeking free status following an *outbreak* and for the maintenance of BT status is also provided.~~

B~~T~~luetongue is a *vector*-borne *infection* transmitted by different species of *Culicoides* ~~insects~~ in a range of ecosystems.

The purpose of *surveillance* is the detection of BTV transmission in a country or *zone* and not determination of the status of an individual animal or *herds*. *Surveillance* deals with the evidence of *infection* with BTV in the presence or absence of clinical signs.

An important component of ~~BT~~the epidemiology of bluetongue is ~~vectorial~~ the capacity of its *vector*, which provides a measure of *disease risk* that incorporates *vector* competence, abundance, biting rates, survival rates and extrinsic *incubation period*. However, methods and tools for measuring some of these *vector* factors remain to be developed, particularly in a field context. Therefore, *surveillance* for ~~BT~~bluetongue should focus on transmission of BTV in domestic ruminants and camelids.

The impact and epidemiology of ~~BT~~bluetongue differ widely in different regions of the world and therefore it is ~~impossible~~ not appropriate to provide specific recommendations for all situations. ~~It is incumbent upon~~ Member Countries should ~~to~~ provide scientific data that explain the epidemiology of ~~BT~~bluetongue in the ~~region~~ country or *zone* concerned and adapt the *surveillance* strategies for defining their ~~*infection*~~ status ~~(free, seasonally free or infected country or *zone*)~~ to the local conditions. There is considerable latitude available to Member Countries to justify their ~~*infection*~~ status at an acceptable level of confidence.

Surveillance for ~~BT~~bluetongue should be in the form of a continuing programme.

~~Article 8.3.17.~~

~~**Surveillance: case definition**~~

~~For the purposes of *surveillance*, a *case* refers to an *animal* infected with BT virus (BTV).~~

~~For the purposes of *international trade*, a distinction should be made between a *case* as defined below and an *animal* that is potentially infectious to *vectors*. The conditions for trade are defined in Articles 8.3.1. to 8.3.15. of this chapter.~~

~~The purpose of *surveillance* is the detection of virus circulation in a country or *zone* and not determination of the status of an individual *animal* or *herds*. *Surveillance* deals not only with the occurrence of clinical signs caused by BTV, but also with the evidence of *infection* with BTV in the absence of clinical signs.~~

~~The following defines the occurrence of BTV *infection*:~~

~~1. BTV has been isolated and identified as such from an *animal* or a product derived from that *animal*, or~~

~~2. viral antigen or viral ribonucleic acid (RNA) specific to one or more of the serotypes of BTV has been identified in samples from one or more *animals* showing clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected *case*, or giving cause for suspicion of previous association or contact with BTV, or~~

~~3. antibodies to structural or nonstructural proteins of BTV that are not a consequence of *vaccination* have been identified in one or more *animals* that either show clinical signs consistent with BT, or epidemiologically linked to a confirmed or suspected *case*, or give cause for suspicion of previous association or contact with BTV.~~

Article 8.3.~~18~~15.

~~Surveillance:~~ ~~G~~general conditions and methods for surveillance

1) A *surveillance* system in accordance with Chapter 1.4. should be under the responsibility of the *Veterinary Authority*. In particular:

   a) a formal and ongoing system for detecting and investigating *outbreaks* of *disease* should be in place;

   b) a procedure should be in place for the rapid collection and transport of samples from suspected *cases* of *infection* with BTV to a *laboratory* for ~~BT~~ diagnosis ~~as described in the *Terrestrial Manual*~~;

   c) a system for recording, managing and analysing diagnostic and *surveillance* data should be in place.

2) The ~~BT~~bluetongue *surveillance* programme should:

   a) in a ~~country/ *zone*~~ free or seasonally free country or *zone*, have ~~include~~ an early warning system which obliges ~~for reporting suspicious *cases*. F~~farmers and workers, who have regular contact with domestic ruminants, as well as diagnosticians, ~~should~~ to report promptly any suspicion of *infection* with BTV to the *Veterinary Authority*.

      ~~They should be supported directly or indirectly (e.g. through private *veterinarians* or *Veterinary para-professionals*) by government information programmes and the *Veterinary Authority*~~. An effective *surveillance* system will periodically identify suspicious *cases* that require follow-up and investigation to confirm or exclude ~~that~~ whether the cause of the condition is BTV. The rate at which such ~~suspicious~~ suspected *cases* are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. All suspected *cases* of ~~BT~~ bluetongue should be investigated immediately and samples should be taken and submitted to a *laboratory*. This requires that sampling kits and other equipment ~~are~~ be available for those responsible for *surveillance*;

AND

   b) conduct random or targeted serological and virological *surveillance* appropriate to the ~~*infection*~~ status of the country or *zone*.

      ~~Generally, the conditions to prevent exposure of susceptible *animals* to BTV-infected *vectors* will be difficult to apply. However, under specific situations, in establishments such as *artificial insemination centres* or *quarantine stations* exposure to *vectors* may be preventable. The testing requirements for animals kept in these facilities are described in Articles 8.3.11. and 8.3.14~~.

Article 8.3.~~19~~16.

Surveillance strategies

The target population for *surveillance* aimed at identification of *disease* ~~and/~~or *infection* should cover susceptible domestic ruminants and camelids, and other susceptible herbivores of epidemiological significance within the country or *zone*. Active and passive *surveillance* for ~~BTV *infection*~~ bluetongue should be ongoing as epidemiologically appropriate. *Surveillance* should be composed of random or targeted approaches using virological, serological and clinical methods appropriate for the ~~*infection*~~ status of the country or *zone*.

~~The strategy employed may be based on *surveillance* using randomised sampling that would demonstrate the absence of BTV *infection* at an acceptable level of confidence. The frequency of sampling should be dependent on the epidemiological situation. Random *surveillance* is conducted using serological tests described in the *Terrestrial Manual*. Positive serological results may be followed up with virological methods as appropriate.~~

~~Targeted *surveillance* (e.g. based on the increased likelihood of *infection* in particular localities or species) may be an appropriate strategy. Virological and serological methods may be used concurrently to define the BTV status of targeted populations~~.

It may be appropriate to focus *surveillance* in an area adjacent to a border of an infected country or infected *zone* for up to 100 kilometres, taking into account relevant ecological or geographical features likely to interrupt the transmission of BTV or the presence in the bordering infected country or infected *zone* of a bluetongue *surveillance* programme (in accordance with Articles 8.3.14. to 8.3.17.) that supports a lesser distance.

A Member Country should justify the *surveillance* strategy chosen as being adequate to detect the presence of ~~BTV~~ *infection* with BTV in accordance with Chapter 1.4. and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical *surveillance* at particular species likely to exhibit clinical signs (e.g. sheep).

Similarly, virological and serological testing may be targeted to species that rarely show clinical signs (e.g. cattle).

In vaccinated populations, serological and virological *surveillance* is necessary to detect the BTV types circulating to ensure that all circulating types are included in the *vaccination* programme.

If a Member Country wishes to declare freedom from ~~BTV~~ *infection* with BTV in a specific *zone*, the design of the *surveillance* strategy ~~would need to~~ should be aimed at the population within the *zone*.

For random surveys, the design of the sampling strategy ~~will need to~~ should incorporate epidemiologically appropriate design prevalence. The sample size selected for testing ~~will need to~~ should be large enough to detect evidence of *infection* if it were to occur at a predetermined minimum rate. The sample size and expected prevalence determine the level of confidence in the results of the survey. The Member Country should justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular ~~needs to~~ should be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the *vaccination* ~~/~~and *infection* history and the different species in the target population.

Irrespective of the testing system employed, *surveillance* system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There ~~needs to~~ should be an effective procedure for following up positive~~s~~ reactions to ultimately determine with a high level of confidence, whether they are indicative of *infection* or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as those which may be epidemiologically linked to it.

The principles involved in *surveillance* for *disease* ~~/~~ or *infection* are technically well defined. The design of *surveillance* programmes to prove the absence of ~~BTV~~ *infection* with BTV ~~/~~ and ~~circulation~~transmission ~~needs to~~ should be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by international trading partners, or excessively costly and logistically complicated. ~~The design of any *surveillance* programme, therefore, requires inputs from professionals competent and experienced in this field.~~

1. Clinical surveillance

   Clinical *surveillance* aims ~~at the detection of~~ to detect clinical signs of ~~BT~~ bluetongue at the *flock* ~~/~~ or *herd* level~~.~~ ~~Whereas significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection should not be underrated~~, particularly during a newly introduced *infection*. In sheep and occasionally goats, clinical signs may include oedema, hyperaemia of mucosal membranes, coronitis and cyanotic tongue.

   ~~BT suspects~~ Suspected *cases* of bluetongue detected by clinical *surveillance* should always be confirmed by *laboratory* testing.

2. Serological surveillance

An active programme of *surveillance* of host populations to detect evidence of BTV transmission is essential to establish BTV status in a country or *zone*. Serological testing of ruminants is one of the most effective methods of detecting the presence of BTV. The species tested should reflect ~~depends on~~ the epidemiology of ~~BTV *infection*~~ bluetongue~~, and the species available~~ ~~in the local area~~. Cattle are usually the most sensitive indicator species. Management variables that may influence likelihood of *infection*, such as the use of insecticides and animal housing, should be considered.

~~*Surveillance* may include serological surveys, for example *abattoir* surveys, the use of cattle as sentinel *animals* (which should be individually identifiable), or a combination of methods. *Surveillance* may also be conducted by sampling and testing of bulk milk using an ELISA, as prescribed in the *Terrestrial Manual*~~.

~~The objective of serological *surveillance* is to detect evidence of BTV circulation~~. Samples should be examined for antibodies against BTV ~~using tests~~ ~~prescribed in the *Terrestrial Manual*~~. Positive ~~BTV antibody~~ test results can have four possible causes:

a) natural *infection* ~~with BTV~~,

b) *vaccination* ~~against BTV~~,

c) maternal antibodies,

d) ~~positive results due to~~ the lack of specificity of the test.

It may be possible to use sera collected for other survey purposes for ~~BTV~~ bluetongue *surveillance*. However, the principles of survey design described in these recommendations and the requirements for a statistically valid survey for the presence of ~~BTV~~ *infection* with BTV should not be compromised.

The results of random or targeted serological surveys are important in providing reliable evidence that no ~~BTV~~ *infection* with BTV is present in a country or *zone*. It is, therefore, essential that the survey is thoroughly documented. It is critical to interpret the results in light of the movement history of the animals being sampled.

Serological *surveillance* in a free *zone* should target those areas that are at highest risk of BTV transmission, based on the results of previous *surveillance* and other information. This will usually be towards the boundaries of the free *zone*. In view of the epidemiology of ~~BTV~~ *infection* with BTV, either random or targeted sampling is suitable to select *herds* ~~and/~~or animals for testing.

~~A *protection zone* within a free country or *zone* should separate it from a potentially infected country or infected *zone*. Serological *surveillance* in a free country or *zone* should be carried out over an appropriate distance from the border with a potentially infected country or infected *zone*, based upon geography, climate, history of *infection* and other relevant factors~~.

Serological *surveillance* in infected *zones* will identify changes in the boundary of the zone, and can also be used to identify the BTV types circulating. In view of the epidemiology of ~~BTV~~ *infection* with BTV, either random or targeted sampling is suitable.

3. Virological surveillance

Isolation and genetic analysis of BTV from a proportion of infected animals ~~is beneficial in terms of providing~~ provides information on serotype and genetic characteristics of the viruses concerned.

Virological *surveillance* ~~using tests~~ ~~described in the *Terrestrial Manual*~~ can be conducted:

a) to identify virus ~~circulation~~transmission in at risk populations,

b) to confirm clinically suspected *cases*,

c) to follow up positive serological results,

d) to better characterise the genotype of circulating virus in a country or *zone*.

4. Sentinel animals

Sentinel animals are a form of targeted *surveillance* with a prospective study design. They are the preferred strategy for ~~BTV~~ bluetongue *surveillance*. They comprise groups of unexposed animals that have not been vaccinated and are managed at fixed locations and sampled regularly to detect new ~~BTV~~ *infections* with BTV.

The primary purpose of a sentinel animal programme is to detect ~~BTV~~ *infections* with BTV occurring at a particular place, for instance sentinel groups may be located on the usual boundaries of infected *zones* to detect changes in distribution of BTV. In addition, sentinel animal programmes allow the timing and dynamics of *infections* to be observed.

A sentinel animal programme should use animals of known source and history of exposure, control management variables such as use of insecticides and animal housing (depending on the epidemiology of ~~BTV~~ bluetongue in the area under consideration), and be flexible in its design in terms of sampling frequency and choice of tests.

Care is necessary in choosing the sites for the sentinel groups. The aim is to maximise the chance of detecting BTV ~~activity~~ transmission at the geographical location for which the sentinel site acts as a sampling point. The effect of secondary factors that may influence events at each location, such as climate, may also be analysed. To avoid bias, sentinel groups should comprise animals selected to be of similar age and susceptibility to ~~BTV~~ *infection~~s~~* with BTV. Cattle are the most appropriate sentinels but other domestic ruminant species may be used. The only feature distinguishing groups of sentinels should be their geographical location.

Sera from sentinel animal programmes should be stored methodically in a serum bank to allow retrospective studies to be conducted in the event of new serotypes being isolated.

The frequency of sampling will depend on the reason for choosing the sampling site. In endemic areas, virus isolation will allow monitoring of the serotypes and genotypes of BTV circulating during each time period. The borders between infected and ~~non~~ uninfected areas can be defined by serological detection of *infective period*. Monthly sampling intervals are frequently used. Sentinels in declared free *zones* add to confidence that ~~BTV~~ *infection~~s~~* with BTV ~~are~~ is not occurring unobserved. In such cases, sampling prior to and after the possible period of transmission is sufficient.

Definitive information on BTV~~s~~ circulating in a country or *zone* is provided by isolation and identification of the viruses. If virus isolation is required, sentinels should be sampled at sufficiently frequent intervals to ensure that samples are collected during the period of viraemia.

5. Vector surveillance

BTV is transmitted between ruminant hosts by species of *Culicoides* which vary across the world. It is therefore important to be able to identify potential *vector* species accurately although many such species are closely related and difficult to differentiate with certainty.

~~The main purpose of~~ *Vector surveillance* ~~is~~ aims to demonstrate the absence of *vectors* or to determine areas of different levels of risk and local details of seasonality by determining the various *vector* species present in an area, their respective seasonal occurrence, and abundance. *Vector surveillance* has particular relevance to potential areas of spread.

Long term *surveillance* can also be used to assess *vector* ~~suppression~~ abatement measures or to confirm continued absence of *vectors*.

The most effective way of gathering this information should take account of the biology and behavioural characteristics of the local *vector* species of *Culicoides* and may include the use of Onderstepoort-type light traps or similar, operated from dusk to dawn in locations adjacent to domestic ruminants, or the use of drop traps over ruminants ~~*animals*~~.

Vector surveillance should be based on scientific sampling techniques. The choice of the number and type of traps to be used ~~in *vector surveillance*~~ and the frequency of their use should take into account the size and ecological characteristics of the area to be surveyed.

The operation of *vector surveillance* sites at the same locations as sentinel animals is advisable.

The use of a *vector surveillance* system to detect the presence of circulating virus is not recommended as a routine procedure as the typically low *vector infection* rates mean that such detections can be rare.

~~Other *surveillance* strategies (e.g. the use of sentinel *animals* of domestic ruminants) are preferred to detect virus circulation~~.

Animal-based *surveillance* strategies are preferred to detect virus transmission.

Article 8.3.~~1920~~17.

Documentation of BTV infection free status

1. Additional surveillance requirements for Member Countries declaring freedom from ~~BTV~~ infection with BTV ~~for the country or zone: additional surveillance procedures~~

   In addition to the general ~~conditions~~ requirements described ~~in the~~ above ~~mentioned articles~~, a Member Country declaring freedom from ~~BTV~~ *infection* with BTV for the entire country or a *zone* should provide evidence for the existence of an effective *surveillance* programme. The strategy and design of the *surveillance* programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in this chapter, to demonstrate absence of ~~BTV~~ *infection* with BTV during the preceding 24 months in susceptible domestic ruminant populations. This requires the support of a *laboratory* able to undertake identification of ~~BTV~~ *infection* with BTV through virus detection and antibody tests ~~described in the *Terrestrial Manual*~~. This *surveillance* should be targeted to ~~non-~~unvaccinated animals. Clinical *surveillance* may be effective in sheep while serological *surveillance* is more appropriate in cattle.

2. Additional requirements for countries or zones that practise vaccination

   Vaccination to prevent the transmission of BTV may be part of a disease control programme. The level of *flock* or *herd* immunity required to prevent transmission will depend on the *flock* or *herd* size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive. The vaccine should also comply with the provisions stipulated for BTV vaccines in the *Terrestrial Manual*. Based on the epidemiology of ~~BTV~~ *infection* with BTV in the country or *zone*, it may be ~~that a decision is reached~~ decided to vaccinate only certain species or other subpopulations.

   In countries or *zones* that practise *vaccination*, ~~there is a need to perform~~ virological and serological tests should be carried out to ensure the absence of virus ~~circulation~~transmission. These tests should be performed on ~~non-~~unvaccinated subpopulations or on sentinels. The tests ~~have to~~ should be repeated at appropriate intervals according to the purpose of the *surveillance* programme. For example, longer intervals may be adequate to confirm endemicity, while shorter intervals may allow on-going demonstration of absence of transmission.

~~Article 8.3.2021.~~

~~**The use and interpretation of serological and virus detection tests**~~

~~1.~~ ~~Serological testing~~

~~Ruminants infected with BTV produce antibodies to structural and non-structural viral proteins, as do *animals* vaccinated with current modified live virus vaccines. Antibodies to the BTV serogroup antigen are detected with high sensitivity and specificity by competitive ELISA (c-ELISA) and to a lesser extent by AGID as described in the *Terrestrial Manual*. Positive c-ELISA results can be confirmed by neutralization assay to identify the infecting serotype(s); however, BTV infected ruminants can produce neutralizing antibodies to serotypes of BTV other than those to which they were exposed (false positive results), especially if they have been infected with multiple serotypes.~~

2. Virus detection

The presence of BTV in ruminant blood and tissues can be detected by virus isolation or polymerase chain reaction (PCR) as described in the *Terrestrial Manual*.

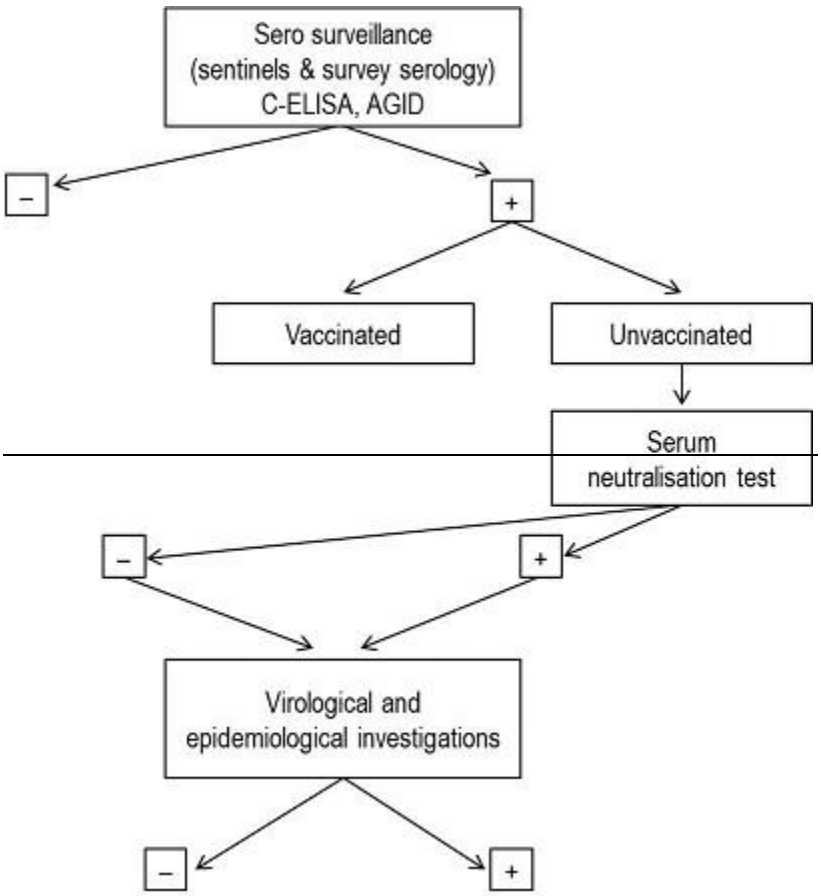
Interpretation of positive and negative results (both true and false) differs markedly between these tests because they detect different aspects of BTV *infection*, specifically (1) infectious BTV (virus isolation) and (2) nucleic acid (PCR). The following are especially relevant to interpretation of PCR assays:

a) The nested PCR assay detects BTV nucleic acid in ruminants long after the clearance of infectious virus. Thus positive PCR results do not necessarily coincide with active *infection* of ruminants. Furthermore, the nested PCR assay is especially prone to template contamination, thus there is considerable risk of false positive results.

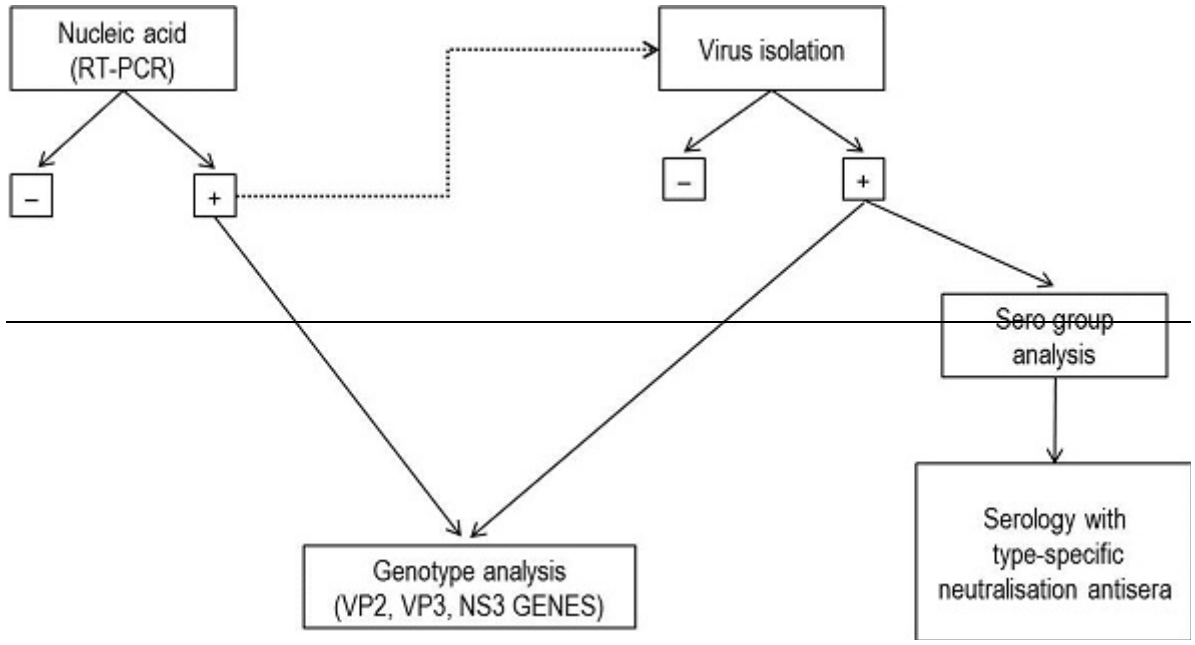
b) PCR procedures other than real time PCR allow sequence analysis of viral amplicons from ruminant tissues, insect *vectors* or virus isolates. These sequence data are useful for creating data bases to facilitate important epidemiological studies, including the possible distinction of field and vaccine virus strains of BTV, genotype characterization of field strains of BTV, and potential genetic divergence of BTV relevant to vaccine and diagnostic testing strategies.

It is essential that BTV isolates are sent regularly to the OIE Reference Laboratories for genetic and antigenic characterization.

Fig. 1. Application of laboratory tests in serological surveillance



~~***Fig 2. Application of laboratory tests in virological surveillance***~~



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